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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,156	04/05/2006	Alain Nepveu	760/11168.304	5760

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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1643	

NOTIFICATION DATE	DELIVERY MODE
10/09/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

afovero@ggd.com
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Office Action Summary	Application No.	Applicant(s)	
	10/535,156	NEPVEU ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,16-19 and 26-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11, 16-19 and 26-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment and Arguments

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

2. Claims 11, 16-19 and 26-28 are pending.

Claims 12-15 and 20-25 have been cancelled.

Claims 11, 26 and 27 have been amended.

Claims 11, 16-19 and 26-28, to the extent protein is detected is examined on the merits.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Rejections

Claim Rejections - 35 USC § 112

4. The **NEW MATTER REJECTION** of claims 11, 16-19 and 26-28 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of Applicants' amendments to the claims. Claims 12-15 and 20 have been cancelled.

5. The rejection of claims 11, 16-20 and 26-28 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in light of Applicants' amendments to the claims. Claims 12-15 have been cancelled.

6. The rejection of claims 11, 16-19 and 26-28 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for detecting the presence or absence of CDP/Cux isoforms comprising contacting a sample with an antibody, which specifically recognizes a truncated CDP/Cux isoform, does not reasonably provide enablement for simultaneously detecting a combination of truncated CDP-Cux variants has been withdrawn in light of Applicants' amendments to the claims. Claims 12-15 and 20 have been cancelled.

7. The rejection of claims 11 and 16-19 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of Applicants' amendments to the claims. Claims 12-15 and 20 have been cancelled.

Claim Rejections - 35 USC § 103

8. The rejection of claims 11, 26 and 27 under 35 U.S.C. 103(a) as being unpatentable over Moon et al. (Molecular and Cellular Biology 21(18): 6332-6345, September 2001/ IDS reference C43 submitted April 5, 2006) is withdrawn. Claims 12, 14, 15 and 20 have been cancelled.

9. The rejection of claims 11, 26 and 27 under 35 U.S.C. 103(a) as being unpatentable over Moon et al. (Int. J. Cancer 100: 429-432, August 2002) is maintained. Claims 12, 14, 15 and 20 have been cancelled.

Maintained and New Grounds of Rejections

Claim Rejections - 35 USC § 102

10. The rejection of claim 11 under 35 U.S.C. 102(b) as being anticipated by Moon et al. (Molecular and Cellular Biology 21(18): 6332-6345, September 2001/ IDS reference C43 submitted April 5, 2006) as evidenced by Goulet (Biol. Chem. 387: 1285-1293, September 2006) is maintained. Claims 12, 14, 15 and 20 have been cancelled.

Applicants assert the claims are now directed to newly discovered p75 polypeptide, hence Moon does not anticipate the claims, see pages 5 and 7 of the Remarks submitted April 23, 2009. This point of view has been carefully considered, but found unpersuasive.

The p75 polypeptide comprises two DNA binding domains, Cut repeat 3 (CR3) and Cut homeodomain (HD). The antibodies of Moon recognized the full length 200-kDA CDP/Cut protein, a 110-kDa protein, as well as 90 kDa protein, see page 6336, An amino-truncated...section. Hence, these same antibodies recognized the p75 polypeptide within the full length protein.

11. The rejection of claim 11 under 35 U.S.C. 102(a) as being anticipated by Moon et al. (Int. J. Cancer 100: 429-432, August 2002) is maintained. Claims 12, 14, 15 and 20 have been cancelled.

Applicants assert the claims are now directed to newly discovered p75 polypeptide, hence Moon does not anticipate the claims, see pages 5 and 7 of the Remarks submitted April 23, 2009. This point of view has been carefully considered, but found unpersuasive.

The antibodies of Moon, α861 anti-CDP/Cux antibodies recognized 3 isoforms, p200, p110 and p100, see Figure 1 on page 430. Hence, these same antibodies recognized the p75 polypeptide within the full length protein.

Claim Rejections - 35 USC § 103

12. Claims 11, 16-19, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moon et al. (Molecular and Cellular Biology 21(18): 6332-6345, September 2001/ IDS reference C43 submitted April 5, 2006), further in view of Nepveu (Gene 270: 1-5, 2001/IDS reference C44 submitted April 5, 2006).

Applicants presented arguments directed to the former 103(a) rejections of record. These rejections are the same as that presented in the 102 rejections. These arguments further assert since p75 is novel and non-obvious, its detection and kits are not obvious, see Remarks, page 7. These points of view have been carefully considered, but found unpersuasive.

The teachings of Moon have been presented in the 102(b) rejection. Moon does not teach the disclosed method of detection wherein the sample tested is derived from blood or breast tissue and said detection methodology is comprised within a kit.

However, Nepveu teaches CDP/Cut proteins' binding activity in mammals generally correlate with cellular proliferation and mutations in the corresponding gene contribute to acute myeloid leukemia and mammary tumors, see page 11, section 19 and entire document. Moreover, although the claims recite a kit and a container for use, no positive recitation of the kit ingredients/elements distinguishes the claim over the reference. Therefore, the reference reads on the claimed kit and container of use. It is noted that kits

traditionally include structural material such as instructions, labeling and promotional material. The container is viewed as a recitation of intended use and therefore is not given patentable weight in comparing the claim with the prior art, see MPEP 706.03(a). Thus the container for use included in a kit or article of manufacture constitutes an "intended use" for that kit or article of manufacture. Thus, the claimed subject matter is considered obvious over the prior art, absent sufficient factual evidence to the contrary.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to assay samples from cancers known to be affected by candidate tumor markers, as well as make a kit containing an antibody that specifically recognizes p75. One of ordinary skill in the art would have been motivated to make a kit because test kits including compounds are packaged for the advantages of convenience and economy for the ordinarily skilled artisan or the practitioner. Kits are conveniently made to reproducibly obtain results under test conditions and it is conventional to assemble necessary reagents including compounds, such as antibody conjugates for the effective treatment of cancer for the convenience of the practitioner and commercial expediency.

13. Claims 11, 16-19, 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moon et al. (Int. J. Cancer 100: 429-432, August 2002), further in view of Nepveu (Gene 270: 1-5, 2001/IDS reference C44 submitted April 5, 2006).

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and therefore is not given patentable weight in comparing the claim with the prior art, see MPEP 706.03(a). Thus the container for use included in a kit or article of manufacture constitutes an "intended use" for that kit or article of manufacture. Thus, the claimed subject matter is considered obvious over the prior art, absent sufficient factual evidence to the contrary.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to assay samples from cancers known to be affected by candidate tumor markers, as well as make a kit containing an antibody that specifically recognizes p75. One of ordinary skill in the art would have been motivated to make a kit because test kits including compounds are packaged for the advantages of convenience and economy for the ordinarily skilled artisan or the practitioner. Kits are conveniently made to reproducibly obtain results under test conditions and it is conventional to assemble necessary reagents including compounds, such as antibody conjugates for the effective treatment of cancer for the convenience of the practitioner and commercial expediency.

14. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached on 7:30 am to 6:30 pm.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alana M. Harris, Ph.D.
28 September 2009
/Alana M. Harris, Ph.D./
Primary Examiner, Art Unit 1643